Exhibit A

From: Meek, Andrew [ETHUS] <ameek@its.jnj.com>
Sent: Thu, 23 Oct 2008 15:33:15 GMT
To: Caro-Rosado, Lissette [ETHUS] <LCaro@its.jnj.com>
Subject: FW: Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

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-----Original Message-----
From: Jaime Sepulveda [mailto:sepu@aol.com]
Sent: Wednesday, October 22, 2008 11:33 PM
To: Granahan, Michele [ETHUS Non-J&J]
Cc: Zipfel, Robert [ETHUS]; Zipfel, Robert [ETHUS]; Meek, Andrew [ETHUS]
Subject: Re: Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

Dr. Robinson and Dr. Kirkemo,

At the light of the FDA warning on mesh complications I find apppropiate to make you aware of the activities devoted to the subject of complications in advanced pelvic surgery using mesh at the preceptorships at South Miami Hospital . Since 2007 the subject of complications associated to the use of Prolift, TVTO, TVT and TVT Secur have been adressed on every professional education activity including every cadaver lab and live surgery preceptorship I have lead.

The following methods and resources have been used:

A copy of the updated monograph with detailed information about complications associated to the use of Prolift has been provided to every physician attending the preceptorships at South Miami Hospital. The monograph is discussed throughout the full day of training. The IFU for Prolift and TVT Secur is included.

A full hour didactic presentation discussing the diagnosis, management and prevention of complications is dedicated separately from the didactics in Prolift technique and indications. The content of the presentation includes

imaging of mesh, removal , complications associated to placement - dissection and best strategies for prevention. During the presentation and afterwards the attendees are prompted to share their experience related to complications and the counseling of patients. It is interactive and peer driven.

The mechanism for reporting complications to the FDA and to EWH&U is discussed. If time allows the attendes get a view of the facilities used to monitor our outcomes through the American College of Surgeons National Surgical Quality Improvement Program. The ACS NSQIP uses a nationally developed methodology to track complications through a blinded review. I believe we are the first institution to use it specifically for the use of mesh in prolapse surgery.

A list of recomended readings and peer reviewed publications is presented at the conclusion of the didactic program on complications. I also include a slide presenting the number of total cases done here and every complication I have handled.

The patient education pamphlet is presented as an aid in the counseling of patients before surgery and its used is encouraged. The pamphlet delineates the most common complications in a clear language that the patient understands. Being in Miami all materials are available in english and spanish. I have also provided on request a copy of the postoperative instructions and postoperative orders used in our service at Miami Urogynecology Center. The postop instructions are also available in both languages.

I have had the privileged opportunity to meet again with some of the physicians trained and go over their outcomes and experiences through advanced users forums. I fly to their location and have a professional education activity consisting on a presentation and an interactive session. It is a good parameter of the relevance of the provided training and the impact on the way care is provided to their patients with prolapse and incontinence.

The use of mesh has given their life back to many women in my area. I have compiled a large number of cases with minimal complications and excellent results. Over my 18 years in a busy urogynecology practice I have learned that once a surgery changes the complications also change , not in numbers but in type. All my patients have been pleased with their meshes and have had no major problems. I am practicing at the most satisfying part of my career thanks to the use of this line of products. Lets not allow distorted perception sabotage a good surgical modality for the care of our patients. Lets continue to lead through evidence based education.

Jaime

L. Sepulveda, MD FACS FACOG

On 10/22/08 3:32 PM, "Granahan, Michele [ETHUS Non-J&J]" <MGranah2@its.jnj.com> wrote:

FINAL - 10/21/08
Email message to Prolapse/SUI preceptors

To Advise of FDA Notification

Dear Preceptor:

On October 21, 2008, the U.S. FDA issued a Public Health Notification to healthcare professionals about complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). The notification was based on 1,000 reports the FDA has received, over a 3-year period, from at least 9 surgical mesh manufacturers. On average, there are about 340,000 procedures per year in the U.S. that use a mesh product to treat prolapse or stress incontinence.

The complications stated in the notification are known risks that can occur with surgical procedures of this type that use mesh. These complications are included in the labeling for our products and we have always communicated these risks in our professional education. As you know, we take the reporting of complications seriously and diligently monitor and report complications associated with the use of our devices.

If you should have any questions, please feel free to contact the ETHICON Medical Affairs department at 1-800-888-9234 extension 3800 or at ETH_MEDICAL_INFO@ETHUS.JNJ.co <mailto:ETH_MEDICAL_INFO@ETHUS.JNJ.co>

Sincerely,

David Robinson, M.D.
Medical Affairs Director

Aaron Kirkemo, M.D.
Associate Medical Affairs Director

Attachment: FDA Notice

<<Document.pdf>>